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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KORNELIA BERGHOF

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EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/463,209

Applicant(s)

BERGHOF ET AL.

Examiner

Juliet C. Switzer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004 and 12 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 82-94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>0105</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. This office action is written in response to applicant's correspondence filed 10/18/04 and 11/12/04. Claims 1-81 have been cancelled and claims 82-94 have been added. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This office action is FINAL.**

2. All previous rejection are WITHDRAWN in view of the cancellation of the previously pending claims. New grounds of rejection are set forth to address the amended claims.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 82, 83, 84, 85, 86, 87, 88, 89, 90, and 91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 82 is indefinite because the claim recites a nucleic acid molecule primer and/or probe, but then later recites "wherein said probe" and so it is not clear if the limitation of the primer and probe are two different molecules (in which case the primer is entirely undefined by any structure) or if the description of the required sequences for the probe also would apply to the primer. All claims which depend from claim 82 are indefinite for this reason as well.

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Claim 82 is further indefinite over the recitation "or sequences complementary thereof" because it is not clear if this is meant to modify the portions of SEQ ID NO: 1 or the entire described probe. All claims which depend from claim 82 are indefinite for this reason as well.

Claim 84 is indefinite because it is not clear if the claim intends to be claiming molecules consisting of eight or nine nucleotides in length or molecules that are ten nucleotides in length wherein eight or nine of the ten nucleotides are successive nucleotides from the delineated regions of SEQ ID NO: 1.

5. Claim 84 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a rejection for NEW MATTER.

Claim 84 is indefinite. This rejection applies to claim 84 when claim 84 is interpreted so as to encompass kits comprising a primer or probe wherein the primer or probe is a molecule that is eight or nine nucleotides in length. The specification provides support for isolated nucleic acid primers or probes that are at least ten nucleotides in length (see for example p. 9-10) but the specification does not provide support for primers or probes that consist of only eight or nine nucleotides.

Claim Rejections - 35 USC § 102

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6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 94 is rejected under 35 U.S.C. 102(b) as being anticipated by Kunsch *et al.* (CA 2194411).

This document is a “laid open” Canadian patent application. When the application is “laid open” all parts of the application as filed become available to the public. In the instant case, the Canadian patent office did not publish the sequence listing for CA 2194411 A1. However, the full sequence listing was available to the public on the day the application was laid open. It is assumed that this sequence listing is identical to that in the CA 2194411 A1 application.

Claim 94 is drawn to a nucleic acid molecule “having” a nucleotide sequence selected from the group consisting of SEQ ID NO: 2, SEQ ID NO: 3 and SEQ ID NO: 4, and a complementary sequence thereof. The transitional phrase “having” is interpreted as being open claim language. Thus, the claim encompasses a nucleic acid comprising one of SEQ ID NO: 2, SEQ ID NO: 3, or SEQ ID NO: 4. Further, the claim recites “a complementary sequence thereof” which encompasses sequences comprise fragments that are complementary to only portions of one of SEQ ID NO: 2, SEQ ID NO: 3, or SEQ ID NO: 4, given the use of the language “a complementary sequence thereof.”

Kunch *et al.* teach an isolated nucleic acid molecule comprising each of SEQ ID NO: 2, SEQ ID NO: 3, and SEQ ID NO: 4.

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For example, SEQ ID NO: 3803 taught by Kunsch *et al.* comprises all of instant SEQ ID NO: 1, of which each of SEQ ID NO: 2, SEQ ID NO: 3, and SEQ ID NO: 4 are fragments. Instant SEQ ID NO: 1 is the complement of 26-196 of Kunsch *et al.*'s SEQ ID NO: 3803.

As another example, SEQ ID NO: 4725 taught by Kunsch *et al.* comprises part of nucleotides 54-83 of instant SEQ ID NO: 1. Nucleotides 106-134 of SEQ ID NO: 4725 are identical to nucleotides 54-82 of SEQ ID NO: 1. Therefore, SEQ ID NO: 4725 also comprises SEQ ID NO: 2.

As a third example, SEQ ID NO: 5094 taught by Kunsch *et al.* comprises nucleotides 100-166 of instant SEQ ID NO: 1, but is shorter than instant SEQ ID NO: 1. Kunsch *et al.*'s SEQ ID NO: 5094 consists of 51 nucleic acids which are identical to nucleotides 83-135 of instant SEQ ID NO: 1. Therefore, SEQ ID NO: 5094 also comprises SEQ ID NO: 4 which are found at positions 102-121 of SEQ ID NO: 1.

Therefore, the teachings of Kunsch *et al.* anticipate claim 94.

8. Claims 82, 84, 85, 86, 87, 88, 89, 92, 93, and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US 5474796).

Brennan teaches an array having thereupon every possible permutation of the 10-mer oligonucleotide. The oligonucleotides are spaced as 7 nm intervals (Col. 9, Example 4, lines 49-55). Thus, Brennan teaches every possible oligonucleotide consisting of 10 successive nucleotides of SEQ ID NO: 1, or of any sequence.

With regard to claim 84, this claim is indefinite (see rejection herein). One possible interpretation of the claim is that the claim encompasses 10mer nucleic acid molecules that have

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eight out of 10 or nine out of 10 nucleotides in common with the ranges of SEQ ID NO: 1.

Brennan teaches every possible 10mer nucleic acid, each as an individual spot on an array.

With regard to claim 85, the molecules taught by Brennan are single stranded.

With regard to claim 86, the molecules taught by Brennan are DNA.

With regard to claim 87, 88, and 89, the molecules taught by Brennan comprise groups for immobilization on a solid phase (they are present immobilized on a solid phase). With regard to claims 88 and 89, these claims further modify the indirect reaction which is recited in claim 87, but do not further limit claim 87 so as to require the group for an indirect reaction to be the element selected from the options listed in claim 87.

This rejection applies to claims 92, 93, and 94 because these claims recite the language “a complementary sequence thereof.” This language is sufficiently broad so as to encompass sequences that are complementary to only fragments of the recited sequences. As Brennan teaches every possible 10-mer oligonucleotide, Brennan teaches many sequences that are considered to be “a complementary sequence” of SEQ ID NO: 1, SEQ ID NO: 2, SEQ ID NO: 3 or SEQ ID NO: 4. Amendment of these claims to clarify that applicant intends to claim the complementary sequence of these would overcome this rejection for these claims.

Amendment of claim 82 to require, for example that the claimed nucleic acid molecule comprises at least 15 successive nucleotides of the recited regions of SEQ ID NO: 1 would overcome this rejection.

Response to Remarks

New grounds of rejection are set forth to address the newly added claims.

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The rejection under 102(b) in view of Kunsch et al. is applied to newly added claim 94 in view of the open claim language used in this claim. Applicant states in the arguments at page 5 that all of the newly added claims are drawn using “consisting of” language, but this does not accurately reflect the language used in claim 94. The language used in claim 94 is open claim language, and thus the rejection in view of Kunsch et al. is maintained. With regard to claim 94 and the arguments on pages 5-6 in the remarks and the declaration under 1.132, the arguments are directed towards the intended use of the molecule. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In the instant case, nucleic acid molecule taught by Kunsch et al. is no different from the instantly claimed nucleic acid molecule (see MPEP 2111.02).

Kunsch et al. is not applied to claims which recite nucleic acid molecules “consisting of” fragments of SEQ ID NO: 1.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Green *et al.* (GenBank L36472, 11 November 1994) provide a nucleic acid sequence which comprises the 5s-23s spacer region of *Staphylococcus aureus*. The sequence taught by Green *et al.* comprises instant SEQ ID NO: 1, except that there are three nucleotides mismatch.

10. No claims are allowed.

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11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached by calling (571) 272-0745.

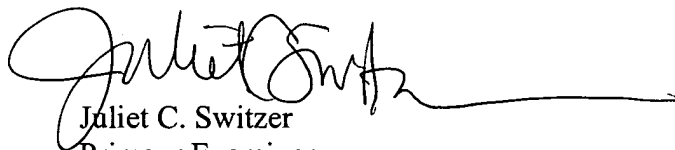
The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the

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USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Juliet C. Switzer
Primary Examiner
Art Unit 1634

January 24, 2005